K120397

SEP 19 2012

510(k) Summary

Company Name: Nihon Kohden Corporation
90 Icon Street
Foothill Ranch, CA 92610

Device Name: Nihon Kohden MEB-2300A Neuropack Evoked Potential and EMG Measuring System

510(k) Sponsor, Contact: Nihon Kohden America, Inc.
90 Icon Street
Foothill Ranch, CA 92610

Steve Geerdes
Director Quality Assurance and Regulatory Affairs
Phone: (949) 580-1555 Ext. 3325
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Revised Summary Date: 09/17/2012

Common Name: Electroencephalograph amplifier (EEG Amplifier)

Classification Names:

Stimulator, Electrical, Evoked Response	882.1870	GWF

Predicate Device(s):

MEB-2200A Neuropack Evoked Potential and EMG Measuring System	K991899

1.0 Description of Device

The MEB-2200A Neuropack Evoked Potential and EMG Measuring System consists of a main acquisition unit, operation control panel, foot switch, electrode junction box (head box), electrical stimulation box and commercially available computer, monitor, printer, keyboard, and mouse. The device also includes optional visual, and auditory stimulators. The monitor, keyboard, and mouse connect to the computer. The computer, electrode junction box, electrical stimulation box, and control panel connect to the main unit. All

components requiring AC power plug into the main unit's built-in, isolated power supply. The main unit plugs into a hospital grade AC power source. All components fit onto a portable cart. A stand is also available for the electrode junction box and electrical stimulation box. Patient data is stored to a encrypted database on the local hard drive or a remote server. The data can also be archived to other commercially available storage medias .

2.0 Intended Use of Device

The Nihon Kohden MEB-2300A Neuropack Evoked Potential and EMG Measuring System is intended to monitor, record and display the bioelectric signals produced by muscles, to stimulate peripheral nerves, and to monitor, record and display the electrical activity produced by nerves to aid the clinician in the diagnosis and prognosis of neuromuscular disease (EMG). The device is also intended to measure and display nerve conduction time by applying a stimulus to a patient's nerve (NCV). The device may use electrical stimulus, visual stimulus, or sound stimulus for use in evoked response measurements (EP). The device may be used to determine autonomic responses as psychological indicators by measuring the electrical resistance of the skin and the tissue path between two electrodes applied to the skin. The device may also measure and record the electrical activity of the patient's brain obtained by placing two or more electrodes on the head (EEG).

The device is intended for use by medical personnel within a hospital, laboratory, clinic or nursing home setting or outside of a medical facility under direct supervision of a medical professional. The device may also be placed in the intensive care unit or operating room for continuous recording.

The device is available for use on any patient as determined by the medical professional including adults and children.

3.0 Technical Characteristics

Setup for the device is performed by a medical professional in the graphical user interface environment of Windows XP or Windows 7. The operator enters patient identification data and specifies the testing protocol. The testing protocol specifies amplifier, acquisition, stimulation, and special parameters for recording data. Recording electrodes and/or sensors are attached to the patient and connected to the corresponding jacks on the junction box. Stimulation electrodes and/or accessories may also be connected. Skin-electrode impedance check is performed from the electrode junction box or the computer software to verify electrode connection and confirm impedance levels for non-invasive recording electrodes. Stimulation is activated to the patient if specified in the protocol.

The device provides 6 or 12 differential channels. Each channel has a pre-amplifier, post-amplifier, low pass filter, and high pass filter. Analog signals from the electrodes and/or sensors are transmitted to a preamplifier for conditioning. The signal output is then fed to the analog to digital converter (ADC).

The digitized electrophysiologic signals may be displayed on the monitor, printed, and/or stored to hard disk drives or other storage media. After completion of the study, the patient is disconnected from the device and medical professional prints and/or stores the data. The data can then be reviewed by a medical professional on the MEB-2300A/K system or another computer containing MEB-2300A/K review software.

4.0 Data Summary

- Non-clinical Testing Data Summary

Testing of the Nihon Kohden MEB-2300A Neuropack Evoked Potential and EMG Measuring System was performed in compliance with Nihon Kohden Corporation design control process. Testing included:

Software and hardware verification and validation, and the device is in compliance with the following voluntary industrial standards:

IEC 60601-1	Part1: General requirements for safety 1998-12
IEC 60601-1, Amendment 1	Part 1: General Requirements for safety, Amendment 1, 1991-11
IEC 60601-1, Amendment 2	Part 1: General Requirements for safety, Amendment 2, 1995-03
IEC 60601-1-1 2nd edition	Part 1-1: General requirements for safety – Collateral standard. Safety requirements for medical electrical systems, 2000-12
IEC 60601-1-2 2nd edition	Part 1-2: General requirements for safety – Collateral standard. Electromagnetic compatibility, 2001-09
IEC 60601-1-2 2nd edition, Amendment 1	Part 1-2: General requirements for safety – Collateral standard. Electromagnetic compatibility. Amendment 1, 2004
IEC 60601-2-40	Part 2-40: Particular Requirements for the safety of electromyographs and evoked response equipment, 1998-02
CAN/CSA-C22.2 No. 601.1-M90	Medical electrical equipment, Part 1: General requirements for safety.
CAN/CSA-C22.2 No. 601.1S1-94	Supplement No. 1-94 to CAN/CSA-C22.2 No. 601-1-M90 Medical Equipment- Part 1:General requirements for safety.

CAN/CSA-C22.2 No. 601.1B-90	Amendment 2 to CAN/CSA-C22.2 No. 601.1-M90 Medical equipment Part 1: General requirements for safety: 2002
CAN/CSA-C22.2 No. 60601-1-1-02	Medical electrical equipment, Part 1-1: General requirements for safety- Collateral: Safety requirements for medical electrical systems, 2006
CAN/CSA-C22.2 No.60601-1-2-03	Medical Electrical Equipment . Part 1-2: General Requirements for Safety . Collateral Standard: Electromagnetic Compatibility . Requirements and Tests (Adopted IEC 60601-1-2:2001, second edition, 2001-09)
CAN/CSA-C22.2 No. 60601-2-40-01	Medical electrical equipment, Part 2-40: Particular requirements for safety of electromyographs and evoked response equipment (adopted 60601-2-40: 1998)

- Clinical Testing Data Summary

  No clinical testing performed for this submission.

5.0 Substantial equivalence comparison

5.1 Intended Use

MEB-2300A NEW DEVICE	MEB-2200A PREDICATE (K991899)
1. Monitor, record and display bioelectric signals produced by muscles and nerves (EMG).	1. Same
2. Measure, record and display nerve conduction time (NCV).	2. Same
3. Determine autonomic responses by measuring electrical resistance of the skin and tissue path	3. Same
4. Measure evoked response using electrical, visual or auditory stimulus (EP).	4. Same
5. Measure, record and display the electrical activity of the patient's brain (EEG).	5. Same

5.2 Physical Characteristics

MEB-2300A NEW DEVICE	MEB-2200A PREDICATE (K991899)

1. Bio-potential signals are amplified, filtered and digitized in the input junction box and sent to the main unit.	1. Same
2. The main unit controls stimulation triggers.	2. Same
3. Waveforms are displayed on monitor and/or printed.	3. Same
4. Waveforms may be permanently stored to storage media for future retrieval.	4. Same

5.3 Target Population and Environment

MEB-2300A NEW DEVICE	MEB-2200A PREDICATE (K991899)
1. Adults and children.	1. Same
2. The device is intended for use by medical personnel within a hospital, laboratory, clinic or nursing home setting or outside of a medical facility under direct supervision of a medical professional. The device may also be placed in the intensive care unit or operating room for continuous recording.	2. Same

5.4 Specifications

	MEB-2300A New Device	MEB-2200A Predicate Device (K991899)
AMPLIFIERS:		
Number of Channels	6, 12 channels	4, 8, 16 channels
Active Electrode jack	4 ports	None
Input Impedance	200 MΩ ±20% (Differential Mode) 1000 MΩ or greater (Common Mode)	Same
Noise	0.6μVrms	Same
Common Mode Rejection Ratio (CMRR)	106 dB or greater (Differential mode) 112 dB or greater (Isolation mode)	Same

Sensitivity	1 to 500 μV/div and 1 to 10 mV/div	Same
Low-cut Filter	0.01 Hz to 3 KHz at 6 dB/octave	Same
High-cut Filter	10 Hz to 20 KHz at 12 dB/octave	Same
Electrode Impedance Check	2, 5, 10, 20, 50kΩ indication	Same
Amplitude Calibration	1, 10, 100 μV, 1, 10mV	Same
AC Filter	50 or 60 Hz	Same
AVERAGERS:		
A/D Converter	18 bits	16 bits
Conversion Speed	5 μs/channel max.	10 μs/channel max.
Monitor Time Base	5 ms/div to 1 s/div	Same
Analysis Time Base	0.1 ms/div to 1 s/div	Same
Time Base Modes	Individually selected for each channel	Same
Delay Time	-10 to +10 div in 1 div steps	Same
Trigger Modes	Recurrent, Random, Foot Switch, Signal,EXT1/2/3/4/5/6, Somato1, Somato3	Recurrent, Random, Foot Switch, Signal, EXT1/2/3/4 Somato1, Somato3, Trig1/2/3/4End
Number of Averages	1 to 9999	Same
Artifact Reject Inhibit Range	±1 to ±5 div or OFF	Same
DISPLAY:		
Display	Color	Same
Number of Waveform Traces	312 Maximum	416 Maximum
Waveform Display Modes	Monitor, Sweep, Analysis	Same
Cursors	2 horizontal, 2 vertical	Same
Scale	5, 10, 15, 20 div	Same

Grid (graticule) Display	Line, Dot, OFF	Same
STIMULATOR COMMON FUNCTIONS:		
Stimulus Modes	Single, Double, Train, Train series (Multi train, Number of train: 1 to 10)	Single, Double, Train
Stimulus Rates	0.1 Hz to 100 Hz	Same
Delay Time	0 to 10 seconds	Same
ELECTRIC STIMULATORS:		
Number of Outputs	4	Same
Stimulus Intensity	0 to 200 mA	0 to 100 mA
Stimulus Pulse Duration	0.01 to 1 ms	Same
AUDITORY STIMULATORS:		
Output Type	Headphone	Same
Stimulus Modes	Click, Tone Burst	Same
Stimulus Phase	Condensation, Rarefaction, Alternating	Same
Stimulus Intensity	0 to 135 dB SPL	Same
Contralateral White Noise Masking	0 to -40 dB, or OFF	Same
Click Pulse Duration	0.1 to 1 ms	Same
Tone Burst Frequency	50 Hz to 10 KHz	Same
Plateau Time	0 to 1000 ms	Same
Rise/Fall Time	0.1 to 10 ms	Same
VISUAL STIMULATORS:		
Stimulus Modes	Pattern Reversal, Flash (with LED goggles), External Visual Stimulation	Same

Patterns	Checkerboard, Horizontal Bars, Vertical Bars	Same
Number of Horizontal Divisions	4, 8, 16, 32, 64, 128	Same
RECORDER:		
Recording Mode	Hard Copy, Review, Report	Same
DIMENSIONS / WEIGHT:		
Main Unit	390 (W) x 55 (H) x 304 (D) mm 3.2 kg	670 (W) x 1320 (H) x 800 (D) mm 14.3 kg
Electrode Junction Box	180 (W) x 56.5 (H) x 234.5 (D) mm 1.5 kg	4/8channels :210 (W) x 180 (H) x 75 (D) mm 1.8kg 16 channels: 257(W) x 182(H) x 68D) mm 2.4kg
Power Unit	The Main Unit includes Power Unit.	Same
POWER REQUIREMENTS:		
Line Voltage	100-120 V AC,220-240V AC	117 V AC
Line Frequency	50/60 Hz	Same
Power Input	Less than 75 VA	Less than 450 VA
ENVIRONMENT:		
Operating Temperature	10 to 35 °C	Same
Storage Temperature	-20 to +65 °C	-20 to +60 °C
Operating Humidity	30 to 80%	20 to 80%
Storage Humidity	10 to 95%	20 to 80%
Operating Atmospheric Pressure	700 to 1060 hPa	Same
Storage Atmospheric Pressure	700 to 1060 hPa	Same

TEST PROTOCOLS AVAILABLE:		
Somatosensory evoked potential	SEP (somatosensory evoked potential) SSEP (short-latency smoatosensory evoked potential) ECG-SSEP (ECG triggered SSEP) ESCP (evoked spinal cord potential) ELECTRIC (customizable protocol)	Same
Auditory evoked potential	ABR (auditory brainstem response) MLR (middle latency response) SVR (slow vertex response) ECOCHG (eletrocochlegram) AUDITORY (customizable protocol)	Same
Visual evoked potential	PR-VEP (pattern reversal visual evoked potential LED-VEP (LED visual evoked potential) EXT-VEP (External stimulator visual evoked potential) ERG (Electroretinogram) EOG (Electroculogram) VISUAL (customizable protocol)	Same
EMG (electromyogram)	EMG (electromyogram) EMG 2(electromyogram2) QEMG (Quantitative EMG) SF EMG (single fiber EMG) MACRO (macro EMG)	EMG (electromyogram) QEMG (Quantitative EMG) SF EMG (single fiber EMG) MACRO (macro EMG)

Nerve Conduction	MCS (motor nerve conduction) SCS (sensory nerve conduction) NCS (nerve conduction studies) REP.STIM (repetitive stimulation) F-WAVE H-REFLEX (monosynaptic reflex H-wave) BLINK (blink reflex) COLLISION (collision method)	MCS (motor nerve conduction) SCS (sensory nerve conduction) REP.STIM (repetitive stimulation) F-WAVE H-REFLEX (monosynaptic reflex H-wave) BLINK (blink reflex) COLLISION (collision method)
Autonomic Nervous System	MICRO-N (microneurography of sympathetic nerve activity) SSR (Sympathetic skin response) R-R Interval	Same
Event related potentials	P-300 (Long latency potential) MRCP (Movement-related cortical potential) CNV (Contingent negative variation)	Same
Trend Monitoring	IOM	Same

5.5 Differences

	MEB-2300A New Device	**MEB-2200A Predicate Device**	**Rationale for Change**
Number of Channels	6, 12 channels	4,8,16 channels	Number of channels of each electrode junction box increases as follows, - 4 to 6 - 8 to 12 - 16 to (32 pending, it is not available yet.)
Active Electrode jack	4 ports	None	Noise is highly reduced by active electrode system.
A/D Converter	18 bits	16 bits	Higher resolution
Conversion Speed	5 μs/channel max.	10 μs/channel max.	Higher sampling speed
Number of Waveform Traces	312 Maximum (26/channel x 12)	416 Maximum (26/channel x 16)	Number of waveform traces per channel remains the same.
Stimulus Modes	Single, Double, Train, Train series (Multi train, Number of train: 2 to 10)	Single, Double, Train	Train series is added.
Trigger Modes	Recurrent, Random, Foot Switch, Signal,EXT1/2/3/4/5/6, Somato1, Somato3	Recurrent, Random, Foot Switch, Signal, EXT1/2/3/4 Somato1, Somato3, Trig1/2/3/4End	External trigger input increases and connectable external device also increases. As a result, complex waveform can be acquired. Train series was required but not available in current device. Therefore, "trig 1/2/3/4End" was used as substitute for train series.
Stimulus Intensity	0 to 200 mA	0 to 100 mA	More stimulus intensity. NIM-Spine by Medtronic (K#031510) also output the intensity up to 200mA.

	MEB-2300A New Device	**MEB-2200A Predicate Device**	**Rationale for Change**
EMG (electromyogram)	EMG (electromyogram) EMG 2(electromyogram2) QEMG (Quantitative EMG) SF EMG (single fiber EMG) MACRO (macro EMG)	EMG (electromyogram) QEMG SF EMG (single fiber EMG) MACRO (macro EMG)	EMG2: Measuring mode with up to 4 measurement settings available EMG: Only one measurement setting
Nerve Conduction	MCS (motor nerve conduction) SCS (sensory nerve conduction) NCS (nerve conduction studies) REP.STIM (repetitive stimulation) F-WAVE H-REFLEX (monosynaptic reflex H-wave) BLINK (blink reflex) COLLISION (collision method)	MCS (motor nerve conduction) SCS (sensory nerve conduction) REP.STIM (repetitive stimulation) F-WAVE H-REFLEX (monosynaptic reflex H-wave) BLINK (blink reflex) COLLISION (collision method)	MCS, SCS, and T-WAVE are integrated in one program as NCS for efficient routine examination.

6.0 Conclusions

The safety and effectiveness of the Nihon Kohden MEB-2300 was demonstrated by testing in compliance with the Design Control process. The intended use and technology of the Nihon Kohden MEB-2300A is equivalent to the predicate devices MEB-200A. No new questions of safety or effectiveness are raised.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

SEP 19 2012

Nihon Kohden America, Inc.
c/o Mr. Steve Geerdes
Director of Regulatory Affairs and Quality Assurance
90 Icon Street
Foothill Ranch, CA 92610

Re: K120397
Trade/Device Name: MEB-2300A Neuropack Evoked
Regulation Number: 21 CFR 882.1870
Regulation Name: Evoked Response Electrical Stimulator
Regulatory Class: Class II
Product Code: GWF, GWE, GWJ, GWQ, GZO, IKN
Dated: September 4, 2012
Received: September 5, 2012

Dear Mr. Steve Geerdes:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Jessica Alexander

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K120397

Device Name: MEB-2300A Neuropack Evoked Potential and EMG Measuring System

Indications For Use:

The Nihon Kohden MEB-2300A Neuropack Evoked Potential and EMG Measuring System is intended to monitor, record and display the bioelectric signals produced by muscles, to stimulate peripheral nerves, and to monitor, record and display the electrical activity produced by nerves to aid the clinician in the diagnosis and prognosis of neuromuscular disease (EMG). The device is also intended to measure and display nerve conduction time by applying a stimulus to a patient's nerve (NCV). The device may use electrical stimulus, visual stimulus, or sound stimulus for use in evoked response measurements (EP). The device may be used to determine autonomic responses as psychological indicators by measuring the electrical resistance of the skin and the tissue path between two electrodes applied to the skin. The device may also measure and record the electrical activity of the patient's brain obtained by placing two or more electrodes on the head (EEG).

The device is intended for' use by medical personnel within a hospital, laboratory, clinic or nursing home setting or outside of a medical facility under direct supervision of a medical professional. The device may also be placed in the intensive care unit or operating room for continuous recording.

The device is available for use on any patient as determined by the medical professional including adults and children.

Prescription Use __X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

John Grimes, Ph.D.

(Division Sign-Off)

Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

510(k) Number K120397